IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of:

Akintade Oyedele Dare.

Serial No.: 09/741,426 Group Art Unit: 1634

Filed: December 21, 2000 Examiner: Goldberg

For: Method and Kit for Quantitating Genomic DNA Damage and Repair Capacity

January 3, 2003

DECLARATION UNDER TO 37 CFR §1.131
TO SWEAR BEHIND A REFERENCE

Commissioner of Patent
and Trademarks
Washington, D.C. 20231

Sir:

The undersigned, Akintade O. Dare, Ph.D., in support of conception and actual reduction to practice of our claimed invention before the effective date of the Pierce Instructions, dated July 1999, which the examiner has cited as a reference in the above-referenced application, declare and affirm under the provisions of 37 CFR § 131 that I am competent to testify as a witness under United States laws, that the statements herein are true and correct, and that the statements herein are made upon first-hand knowledge.

1. I am the original, sole, and first inventor of the subject matter of claims 1-11, 14-15, and 18-19 of the above-identified patent application, as well as other subject matter described in the attached documents.

2. At least as early as before July 1999, I conceived and reduced to practice the inventions defined by the aforestated claims by developing and testing in the United States various physical embodiments of the inventions. As support therefor, I attest that the attached, below-described and attached documents are true and accurate records and that these records were contemporaneously generated in the course of my development of physical embodiments of the aforestated inventions on or about the dates indicated therein.

3. My work in conceiving and reducing the aforestated inventions began in or about October and December 1997 and was completed well before July 1999, as evidenced by the attached records. These records were generated and my work was carried out in Atlanta, Georgia, partly at Emory University.

4. Phase I experiments relative to Protamine sulfate are described at p. 1000 of Attachment A and Phase III-A experiments relative to Reacti-bind are described at p. 1011 of Attachment C.

5. In or about January 23, 1998, during Phase VIII-C experiments, I began investigating ways to improve DNA binding efficiency using Reacti-bind solutions, as evidenced by entries in my laboratory notebook (1st and 2nd handwritten paragraphs, p. 1073, Attachment E) and test results (pp. 1073-1077, Attachment E).

6. On January 26, 1998, during my experimentation, I observed that introduction of Reacti-bind solution to a DNA solution improved DNA binding affinity to the wells of a microtiter plate. (p. 1078, Attachment F). Increased binding is evidenced by corresponding test results, shown at pp. 1079-1081, Attachment F. My work also included investigation on January 27th concerning DNA binding to Amino plates (Attachment G), and an investigation on January 28th concerning whether Reacti-bind improved DNA binding to such plates (Attachment H).

7. Attachments J-K, pp. 1132-1140, show my work in 1998 in investigating the effects on binding affinity using different amounts of Reacti-bind and varying incubation times.

8. Attachment N, pp.1111-1124, shows my work in 1998 investigating a comparison of DNA binding efficiency of Reacti-bind and Protamine sulfate.

9. Attachments O and P show my investigation of incubation time and temperature on Reacti-bind binding efficiency of DNA.

10. Attachment Q, p. 1106 in particular, shows my work in December 1998 determining the impact of various amounts of Reacti-bind on DNA binding efficiency, as reflected by optical density measurements.

11. Attachment R shows my work in February 1998 relative to the use of Reacti-bind on DNA binding efficiency.

12. Attachment S, T, U, V, W, X, show test data that I generated from June through December 1998 that helped refine the specific amounts or concentrations of Reacti-bind needed to optimize DNA binding efficiency.

13. Based on the results of my research, as evidenced by contemporaneously generated research notes, I conceived and reduced to practiced the invention of claims 1-11, 14-15, and 18-19 in or about December 1998, which is well before the July 1999 date of the Pierce reference cited by the examiner.

14. Further, on or about November 1998, I met personally with Lee A. Sylvers, Ph.D., Manager, Molecular Biology R & D, during the Neuro Science Annual meeting held at the Los Angeles Convention Center. During that meeting, I discussed with Dr. Sylvers my research involving improved DNA binding efficiency brought about using Reacti-bind mixtures with DNA solutions. During that meeting, Dr. Sylvers gave me his business card (Attachment Y) whereupon I wrote thereon in November 1998 the notation "on DNA Binding Efficiency" to memorialize at least part of the subject matter of our discussion. Based on the aforestated events, it is my belief that the Example Protocol described in the July 1999 Pierce reference cited by the examiner was derived from my own work, and thus cannot be anticipatory or suggestive of my invention under the United States patent laws.

The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and may jeopardize the validity of the application or any patent issuing thereon, declare that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true.

01/04/03
Date

Dr. Akintade O. Dare